(Cost-)effectiveness of MicroShunt versus Trabeculectomy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20100

Source
Nationaal Trial Register

Brief title
MS vs TE

Health condition

Primary open-angle glaucoma

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw 852001908

Intervention

Outcome measures

Primary outcome

The primary outcome measure is intraocular pressure after 12 months of follow-up.

Secondary outcome

Secondary outcome measures are best corrected visual acuity, glaucoma medications, safety

(complications and surgical interventions), visual fields, vision-related quality of life and generic health-related quality of life, and costs, cost-effectiveness and budget impact

Study description

Background summary

The standard surgical treatment for glaucoma is trabeculectomy. The PRESERFLO™ (formerly InnFocus) MicroShunt is a new, minimally invasive drainage device which has been suggested to result in similar intraocular pressure lowering, but with faster visual recovery and less complications and postoperative interventions. However, this is based on limited evidence, underscoring the need for a randomized controlled trial.The objective of this project is to aid in deciding on the use of the MicroShunt in glaucoma surgery by assessing its efficacy and cost-effectiveness in patients with primary open-angle glaucoma (POAG) compared to trabeculectomy.
This is a multicenter, randomized, single blind, non-inferiority, interventional clinical trial, involving 10 medical centres in the Netherlands.

Study objective

The hypothesis is that the MicroShunt will lead to a similar IOP lowering compared to trabeculectomy, and will be a cost-effective
alternative for trabeculectomy.

Study design

preoperative visit, 1 day, 1 week, 4 weeks, 3, 6, 9 and 12 months postoperative.

Intervention

MicroShunt implantation augmented mitomycin C versus a standard trabeculectomy augmented with mitomycin C.

Contacts

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Eligibility criteria

Inclusion criteria

Caucasian, primary open angle glaucoma patients, between 18 and 80 years old, requiring standard trabeculectomy.

Exclusion criteria

1. Patient unwilling or unable to give informed consent, unwilling to accept randomization or inability to complete follow-up (e.g. hospital visits) or comply with study procedures
2. Secondary glaucoma.
3. Previous incisional surgery of the subject eye. Previous uncomplicated clear corneal cataract surgery is allowed >6 months prior to the surgery.
4. Poor vision in either the study or fellow eye.
5. Any ocular comorbidities that could affect the visual field. .
6. Chronic or recurrent uveitis.
7. Need for glaucoma surgery combined with other ocular procedures or anticipated need for additional ocular surgery.
8. Anatomical factors that increase the risk of complicated surgery.
9. Conditions that increase the risk of endophthalmitis.
10. Contraindication or allergy to mitomycin C.
11. Any contraindication to tube placement.
12. Use of oral hypotensive glaucoma medications for treatment of the fellow eye.
13. Prior ocular laser treatment within 3 months of the surgery.
14. Corneal thickness <450um or >620microns.
15. Conditions associated with elevated episcleral venous pressure such as active thyroid orbitopathy.
16. Among patients in whom both eyes are eligible only the first eye is undergoing surgical treatment is enrolled in the study.
17. Participation in another clinical study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-02-2020
Enrollment:	196
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-02-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52755
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8356
CCMO	NL68964.068.19
OMON	NL-OMON52755

Study results